

# Notice of Allowability

Application No.

09/888,072

Examiner

Anand U Desai, Ph.D.

Applicant(s)

GREENWALD ET AL.

Art Unit

1653

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_\_.
2. ☒ The allowed claim(s) is/are 1,5,9,11,15-17 and 19-26.
3. ☒ The drawings filed on 22 June 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20040723.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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### **DETAILED ACTION**

1. This office action is in response to amendment filed on April 30, 2004. New claims 17-26 have been added. Claims 1, 5, 9, 11, 15-26 are currently pending and are under examination.

### **EXAMINER'S AMENDMENT**

2. An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

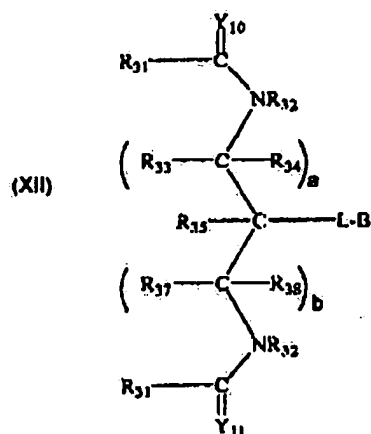
Authorization for this examiner's amendment was given in a telephone interview with Mr. Michael N. Mercanti on July 23, 2004.

#### **Examiner's Amendment to the Claims:**

2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
10. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).

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15. (Currently amended) A method of preparing a polymeric conjugate, comprising reacting a compound of formula (XII)



wherein

$R_{31}$  is a linear or branched polymer residue;

$Y_{10}$  and  $Y_{11}$  are independently O, S, or  $NR_{40}$ ;

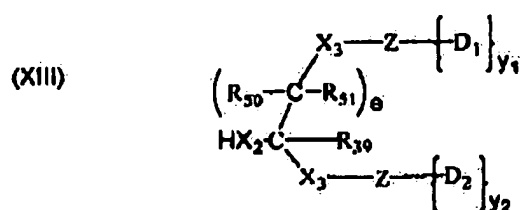
L is an amino acid residue or a bifunctional linker;

$R_{32}$ ,  $R_{33}$ ,  $R_{34}$ ,  $R_{35}$ ,  $R_{37}$ ,  $R_{38}$ , and  $R_{40}$  are independently selected from the group consisting of hydrogen,  $C_{1-6}$  alkyls,  $C_{3-12}$  branched alkyls,  $C_{3-8}$  cycloalkyls,  $C_{1-6}$  substituted alkyls,  $C_{3-8}$  substituted cycloalkyls, aryls, substituted aryls, aralkyls,  $C_{1-6}$  heteroalkyls and substituted  $C_{1-6}$  heteroalkyls;

a and b are each independently a positive integer, and

B is a leaving group;

with a compound of the formula (XIII)

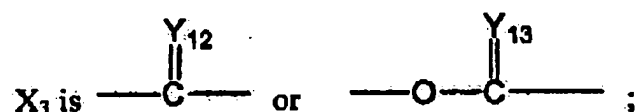


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wherein

 $X_2$  is O, S, or  $NR_{41}$ ;

$R_{39}$ ,  $R_{41}$ ,  $R_{50}$  and  $R_{51}$  are independently selected from the group consisting of hydrogen,  $C_{1-6}$  alkyls,  $C_{3-12}$  branched alkyls,  $C_{3-8}$  cycloalkyls,  $C_{1-6}$  substituted alkyls,  $C_{3-8}$  substituted cycloalkyls, aryls, substituted aryls, aralkyls,  $C_{1-6}$  heteroalkyls and substituted  $C_{1-6}$  heteroalkyls;

wherein  $Y_{12}$  and  $Y_{13}$  are independently O, S, or  $NR_{41}$ ;

$Z$  is selected from the group consisting of a bond, a moiety that is actively transported into a target cell, a hydrophobic moiety, and combinations thereof;

$D_1$  and  $D_2$  are independently selected from the group consisting of OH, a residue of a hydroxyl, a residue of an amine-containing moiety and a leaving group;

 $e$  is a positive integer; and $y_1$  and  $y_2$  are independently selected positive integers;

under conditions sufficient to cause a substitution reaction in which the compound of formula (X) is formed, and isolating the polymer conjugate of formula (X).

18. (Cancelled).

24. (Currently amended) The compound of claim 1, wherein  $R_{32}$ - $R_{35}$ ,  $R_{37}$ - $R_{40}$ ,  $R_{50}$ , and  $R_{51}$  are each hydrogen.

***Claim Rejections - 35 USC § 112***

3. Upon review of Applicant's amendment there are no outstanding 35 U.S.C § 112 rejections.

***Claim Rejections - 35 USC § 103***

4. Upon review of Applicant's amendment the 35 U.S.C. § 103 rejection of claims 1, 5, 9, 11, 15, and 16 are withdrawn.

***Allowable Subject Matter***

5. Claims 1, 5, 9, 11, 15-17, and 19-26 are allowable.
6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

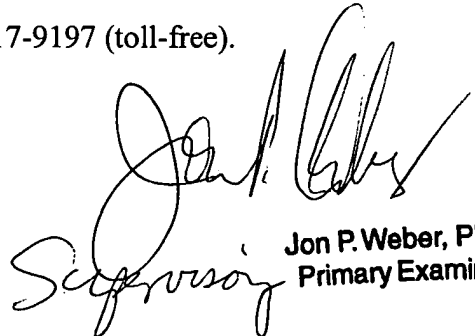
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 23, 2004

A handwritten signature in black ink, appearing to be 'AD' or similar, located below the date.A large, stylized handwritten signature in black ink, likely belonging to Jon P. Weber, located above the printed name.

Jon P. Weber, Ph.D.  
Primary Examiner